

SUCCINYLCHOLINE CHLORIDE- succinylcholine chloride injection
Renaissance Lakewood LLC

Succinylcholine Chloride Injection USP, 20 mg/mL

WARNING

RISK OF CARDIAC ARREST FROM HYPERKALEMIC RHABDOMYOLYSIS

There have been rare reports of acute rhabdomyolysis with hyperkalemia followed by ventricular dysrhythmias, cardiac arrest and death after the administration of succinylcholine to apparently healthy pediatric patients who were subsequently found to have undiagnosed skeletal muscle myopathy, most frequently Duchenne's muscular dystrophy.

This syndrome often presents as peaked T-waves and sudden cardiac arrest within minutes after the administration of the drug in healthy appearing pediatric patients (usually, but not exclusively, males, and most frequently 8 years of age or younger). There have also been reports in adolescents.

Therefore, when a healthy appearing infant or child develops cardiac arrest soon after administration of succinylcholine, not felt to be due to inadequate ventilation, oxygenation or anesthetic overdose, immediate treatment for hyperkalemia should be instituted. This should include administration of intravenous calcium, bicarbonate, and glucose with insulin, with hyperventilation. Due to the abrupt onset of this syndrome, routine resuscitative measures are likely to be unsuccessful. However, extraordinary and prolonged resuscitative efforts have resulted in successful resuscitation in some reported cases. In addition, in the presence of signs of malignant hyperthermia, appropriate treatment should be instituted concurrently.

Since there may be no signs or symptoms to alert the practitioner to which patients are at risk, it is recommended that the use of succinylcholine in pediatric patients should be reserved for emergency intubation or instances where immediate securing of the airway is necessary, e.g., laryngospasm, difficult airway, full stomach, or for intramuscular use when a suitable vein is inaccessible (see PRECAUTIONS: Pediatric Use and DOSAGE AND ADMINISTRATION).

Primary package for Succinylcholine

Rx Only

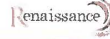
Succinylcholine

Chloride Injection, USP

200 mg/10 mL (20 mg/mL)

For Intravenous or Intramuscular Use
Store in refrigerator 2° to 8°C (36° to 46°F).
25 x 10 mL Multiple-Dose Vials

Manufactured for:
Renaissance SSA, LLC
Newtown, PA 18940



USE ASEPTIC TECHNIQUE

WARNING: Succinylcholine chloride is a potent drug which may cause respiratory depression. Facilities must be immediately available for artificial respiration.

Store in refrigerator 2° to 8°C (38° to 48°F).

REV. 06/17



Store in refrigerator 2° to 8°C (36° to 46°F).
 See insert for dosage, precautions, indications and
 directions for use.

NDC 70655-015-25

Rx Only

Succinylcholine

200 mg/10 mL (20 mg/mL)

For Intravenous or Intramuscular Use

**Store in refrigerator
2° to 8°C (36° to 46°F).**

25 x 10 mL Multiple-Dose Vials



COATED
AREA

EXTERIOR ART

SUCCINYLCHOLINE CHLORIDE

succinylcholine chloride injection

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:49396-0152
Route of Administration	PARENTERAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SUCCINYLCHOLINE CHLORIDE (UNII: I9L0DDD30I) (SUCCINYLCHOLINE - UNII:J2R869A8YF)	SUCCINYLCHOLINE CHLORIDE	200 mg in 10 mL

Inactive Ingredients

Ingredient Name	Strength
PROPYLPARABEN (UNII: Z8IX2SC1OH)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49396-0152-2	6 in 1 BOX	10/01/2018	
1		25 in 1 CARTON		
1		10 mL in 1 VIAL; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA210231	10/01/2018	

Labeler - Renaissance Lakewood LLC (077744035)

Registrant - Renaissance Lakewood LLC (077744035)

Establishment

Name	Address	ID/FEI	Business Operations
Renaissance Lakewood LLC		077744035	manufacture(49396-0152) , analysis(49396-0152)